

## **REMARKS**

### **Claim Rejections – 35 USC §103**

Claims 54-66, 68, 69 and 74-79 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,454,365 to Bonutti, and claims 54-58, 64-70 and 74-76 have been rejected as being unpatentable over U.S. Patent No. 5,885,258 to Sachdeva.

### **Claim Amendments**

The Applicant has cancelled claims 54, 64 and 75-79 without prejudice for possible submission and consideration in a continuing application. Independent claims 59 and 75 have been amended to recite further features associated with the claimed invention. Dependent claims 55-58, 65, 68, 71 and 74 have been amended to depend from independent claim 59. Dependent claims 66 and 69 have been rewritten in independent form and have also been amended to recite further features associated with the claimed invention. Additionally, new claims 94-103 have been added. Support for new claims 94-103 is found, for example, on page 10, line 18 to page 12, line 9 and Figures 2, 5 and 6 of the as-filed application.

### **Arguments in Support of Patentability**

The Office Action admits that Bonutti and Sachdeva fail to disclose an instrument including no more than two oppositely and equally spaced transverse projections that extend in a uni-axial direction along a single transverse axis. (See page 4, lines 12-14; page 6, line 21 to page 7, line 1). Nevertheless, the Office Action asserts that “[w]hile Bonutti does not explicitly teach two oppositely spaced transverse projections, Bonutti does disclose that the number of projections may vary and that they may be spaced equally . . . in order to provide varying expansion” and that “[i]t would have been obvious . . . to construct the Bonutti device with two, oppositely spaced projections in view of Bonutti’s own disclosure . . . to provide varying expansion.” (Page 4, lines 17-22; citations omitted). Similarly, the Office Action asserts that “[w]hile Sachdeva et al. does (sic) not explicitly teach two oppositely spaced transverse projections, Sachdeva et al. does (sic) disclose that the amount of slots, and consequently projections, may vary depending on the intended function of the device” and that “[i]t would have been obvious . . . to construct the Sachdeva et al. device with two, oppositely spaced projections in view of Sachdeva et al.’s own disclosure . . . depending on the intended function.” (Page 7, lines 3-9; citations omitted).

**Independent Claim 59 and Dependent Claims 55-58, 60-63, 65, 68, 71-74 and 94-97**

Independent claim 59 has been solely rejected as being unpatentable over Bonutti. The Applicant has amended independent claim 59 to recite, among other elements and features, an elongate member including a deformable distal portion that is outwardly deformed to define “at least one but no more than two transverse projections”, with “each of said transverse projections arranged along a single transverse axis, and wherein formation of said transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis”, and wherein the elongate member comprises an inner actuator member disposed within an outer sleeve member with the distal portion of the sleeve member being outwardly deformed to define the transverse projections in response to relative displacement between the actuator member and the sleeve member, and “wherein said deformable distal portion comprises at least one flexible strip of material having a length extending along said longitudinal axis, said flexible strip of material having an outwardly buckled configuration defining said at least one transverse projection, said flexible strip of material configured such that said relative displacement between said actuator member and said sleeve member transitions said flexible strip of material to said outwardly buckled configuration and provides said transverse projection with an arc-shaped outer curvature extending along said length of said flexible strip of material and configured to bear against vertebral bone”.

The Applicant notes that the subject matter of dependent claim 64 has been incorporated into independent claim 59, with claim 64 having been cancelled without prejudice. Additionally, support for the amendments incorporated into independent claim 59 is found, for example, on page 10, line 18 to page 12, line 9; page 20, lines 5-21; page 34, line 13 to page 35, line 8; and Figures 5, 6 and 12 of the as-filed application. As illustrated in Figures 6 and 12, the flexible strips of material 54, 56 having an outwardly buckled configuration defining the transverse projections 198a, 198b, with the flexible strips of material 54, 56 configured such that the outwardly buckled configuration provides the transverse projections 18a, 198b with an arc-shaped outer curvature extending along the length of the flexible strips of material 54, 56.

With regard to Bonutti, as shown in Figure 1 and 2, the retractor 10 includes an expanding portion 60 having a plurality of expanding arms 62 that are separated by a series of longitudinally extending slots 64. Even assuming arguendo that one of the expanding arms 62

could be construed as a flexible strip of material having an outwardly buckled configuration defining at least one transverse projection, the expanding arms 62 are not configured such that relative displacement between an inner actuator member and an outer sleeve member “transitions said flexible strip of material to said outwardly buckled configuration and provides said transverse projection with an arc-shaped outer curvature extending along said length of said flexible strip of material and configured to bear against vertebral bone”. Instead, as clearly illustrated in Figure 2, when the retractor 10 is expanded, each of the expanding arms 62 is provided with a flat/planar distal portion 72 and a flat/planar proximal portion 74. As should be readily apparent, the flat/planar distal and proximal portions 72, 74 do not provide the expanding arms 62 with “an arc-shaped outer curvature extending along said length of said flexible strip of material”, as recited in independent claim 59. Although the flat/planar distal and proximal portions 72, 74 of the expanding arm 62 are angled relative to one another, the portions 72, 74 do not provide the expanding arm 62 with “an arc-shaped outer curvature” extending along the length of the arm 62 and configured to bear against vertebral bone.

As indicated on page 34, line 13 to page 35, line 8 of the as-filed application, the transverse projections are configured to bear against vertebral bone, and may be “particularly useful, for example, to compact or compress cancellous bone against the inner cortical wall of the vertebral body”. As should be appreciated, providing the transverse projection 198a, 198b with “an arc-shaped outer curvature” extending along a length of the flexible strip of material 54, 56 is particularly suitable for compacting or compressing cancellous bone. Specifically, providing the transverse projections 198a, 198b with an arc-shaped outer curvature tends to provide for a more uniform and distributed compression or compaction force against the cancellous bone along the length of the flexible strip of material 54, 56. Such features are not realized by the flat/planar distal and proximal portions 72, 74 of the expanding arms 62. Instead, the purpose of the expanding arms 62 is “for expanding sub-surface tissue . . . to provide a working space between adjacent arms” (see Abstract), and not to bear against vertebral bone. Specifically, as shown in Figures 6 and 7, “the expanding arms 62 are disposed irregularly circumferentially around the retractor to provide an increased working space or operating area between particular pairs of expanding arms 62. . . . An enlarged working space 81 is formed between the arm 82 and the arm 84 of the sleeve 14a.” (See column 5, lines 58-61). The flat/planar distal and proximal portions 72, 74 of the expanding arms 62 provide increased

visualization of the surgical site and an unobstructed operating passageway for the insertion of surgical instruments within the working space 81 between adjacent pairs of the expanding arms 62, but are not conducive to provide for a more uniform and distributed compression or compaction force against cancellous bone.

The Applicant notes that independent claim 59 was not rejected based on the Sachdeva reference. Nevertheless, the Applicant submits that Sachdeva fails to disclose or suggest that any of the disclosed devices include “an inner actuator member disposed within an outer sleeve member” with “a distal portion of said sleeve member being outwardly deformed . . . in response to relative displacement between said actuator member and said sleeve member”, or that “said relative displacement between said actuator member and said sleeve member transitions said flexible strip of material to said outwardly buckled configuration”, as recited in independent claim 59.

For at least the reasons set forth above, independent claim 59 is submitted to be patentable over Bonutti and Sachdeva. The Applicant therefore respectfully requests withdrawal of the rejection of independent claim 59 and allowance of the same.

Claims 55-58, 60-63, 65, 68, 71-74 and 94-97 depend either directly or indirectly from independent claim 59 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 59. However, further reasons support the patentability of the claims depending from independent claim 59. For example, claim 94 recites that “said deformable distal portion includes a pair of longitudinally extending slots extending along said longitudinal axis and defining said flexible strip of material therebetween, said flexible strip of material having a predetermined shape to provide controlled transitioning to said outwardly buckled configuration, at least one of said longitudinally extending slots having a narrowed area and a widened area extending axially from said narrowed area, said widened area having a greater width relative to said narrowed area to provide said flexible strip of material with a narrowed width which defines a flexion point to control outward deformation of said flexible strip of material to said outwardly buckled configuration”. As will be discussed in detail below with regard to independent claim 66, these features are neither disclosed nor suggested by Bonutti or Sachdeva.

Additionally, claim 95 recites that “said widened area of said slot is defined by an arcuate portion of said slot”, claim 96 recites that “said slot has first and second widened areas with said

narrowed area positioned between said first and second widened areas to provide said slot with an hour-glass shape”, and claim 97 further recites that “said hour-glass shape is defined by a series of arcuate portions of said slot extending along said longitudinal axis”. As will be discussed in detail below with regard to claims 98-100, the features recited in claims 95-97 are neither disclosed nor suggested by Bonutti or Sachdeva.

**Independent Claim 66 and Dependent Claims 67 and 98-100**

Claim 66 has been rejected as being unpatentable over Bonutti and Sachdeva. As indicated above, the Applicant has rewritten claim 66 in independent form, and has amended rewritten independent claim 66 to recite further features associated with the claimed invention. Specifically, independent claim 66 has been amended to recite that “said elongate member comprises an inner actuator member disposed within an outer sleeve member, a distal portion of said sleeve member being outwardly deformed to define said transverse projections in response to relative displacement between said actuator member and said sleeve member”. Independent claim 66 has also been amended to recite “wherein said deformable distal portion includes a pair of longitudinally extending slots extending along said longitudinal axis and defining a longitudinally extending flexible strip of material therebetween that is deformed to an outwardly buckled configuration to define one of said transverse projections, said flexible strip of material having a predetermined shape to provide controlled transitioning to said outwardly buckled configuration, at least one of said longitudinally extending slots having a narrowed area and a widened area extending axially from said narrowed area, said widened area having a greater width relative to said narrowed area to provide said flexible strip of material with a narrowed width which defines a flexion point to control outward deformation of said flexible strip of material to said outwardly buckled configuration”. Support for the amendments incorporated into independent claim 66 is found, for example, on page 10, line 18 to page 12, line 9; page 19, line 18 to page 20, line 21; and Figures 2, 5 and 6 of the as-filed application.

With regard to Bonutti, the distal end portion of the tissue retractor includes a series of rectangular-shaped longitudinally extending slots 64 which in turn define a series of rectangular-shaped expanding arms 62 between adjacent pairs of the longitudinally extending slots 64. (See Figures 1 and 2). However, Bonutti fails to disclose or suggest that either of the longitudinally extending slots 64 define an expanding arm 62 therebetween has “a narrowed area and a

widened area extending axially from said narrowed area”, and with “said widened area having a greater width relative to said narrowed area to provide said flexible strip of material with a narrowed width which defines a flexion point” to control outward deformation of the expanding arm 62. To the contrary, each of the longitudinally extending slots 64 has a rectangular shape defining a uniform shape and width, and clearly do not define “a narrowed area and a widened area extending axially from said narrowed area”. Additionally, each of the expanding arms 62 also has a rectangular shape defining a uniform shape and width, and is not provided with “a narrowed width” via a widened area of one of the longitudinally extending slots 64 to define a flexion point to control outward deformation of the expanding arm 62. Accordingly, the Applicant submits that independent claim 66 recites features that are neither disclosed or suggest by Bonutti.

With regard to Sachdeva, none of the disclosed devices includes “an inner actuator member disposed within an outer sleeve member, a distal portion of said sleeve member being outwardly deformed to define said transverse projections in response to relative displacement between said actuator member and said sleeve member”, as recited in independent claim 66. This position is supported by the fact that the previous version of independent claim 59, which recites this same language, was not rejected based on Sachdeva. Furthermore, the devices disclosed in Sachdeva fail to disclose or suggest other features recited in independent claim 66. Specifically, as shown in Figures 1-4 of Sachdeva, the outwardly deformable strips of material defined between adjacent slots each have a rectangular shape defining a uniform shape and width, and are not provided with “a narrowed width” via a widened area of one of the longitudinally extending slots to define a flexion point to control outward deformation of the strips of material. Accordingly, the Applicant submits that further reasons support the patentability of independent claim 66 over Sachdeva.

For at least the reasons set forth above, independent claim 66 is submitted to be patentable over Bonutti and Sachdeva. The Applicant therefore respectfully requests withdrawal of the rejection of independent claim 66 and allowance of the same.

Claims 67 and 98-100 depend either directly or indirectly from independent claim 66 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 66. However, further reasons support the patentability of the claims depending from independent claim 66. For example, claim 98 recites that “said

widened area of said slot is defined by an arcuate portion of said slot”, claim 99 recites that “said slot has first and second widened areas with said narrowed area positioned between said first and second widened areas to provide said slot with an hour-glass shape”, and claim 100 further recites that “said hour-glass shape is defined by a series of arcuate portions of said slot extending along said longitudinal axis”.

Neither Bonutti nor Sachdeva disclose the features recited in claims 98-100. Instead, the longitudinally extending slots defined by the Bonutti and Sachdeva devices have a rectangular shape defining a uniform width and straight/non-arcuate sides which provide the longitudinally extending strips of material defined between adjacent pairs of the slots with a rectangular shape having straight sides. Indeed, none of the longitudinally extending slots have “an arcuate portion” that defines a widened area of the slot, as recited in claim 98. Additionally, none of the longitudinally extending slots have “first and second widened areas with said narrowed area positioned between said first and second widened areas” to provide the slot with “an hour-glass shape”, as recited in claim 99, or that “said hour-glass shape is defined by a series of arcuate portions of said slot extending along said longitudinal axis”, as recited in claim 100.

**Independent Claim 69 and Dependent Claims 70 and 101-103**

Claim 69 has been rejected as being unpatentable over Bonutti and Sachdeva. As indicated above, the Applicant has rewritten claim 69 in independent form, and has amended rewritten independent claim 69 to recite further features associated with the claimed invention. Specifically, independent claim 69 has been amended to recite that “said elongate member comprises an inner actuator member disposed within an outer sleeve member, a distal portion of said sleeve member being outwardly deformed to define said transverse projections in response to relative displacement between said actuator member and said sleeve member”. Independent claim 69 has also been amended to recite “wherein said deformable distal portion defines a plurality of longitudinally extending slots extending along said longitudinal axis, a pair of said slots defining a longitudinally extending flexible strip of material therebetween that is deformed to an outwardly buckled configuration to define one of said transverse projections, each of said plurality of slots having a predetermined shape to provide controlled outward buckling, at least one of said longitudinally extending slots having a narrowed area and a widened area extending axially from said narrowed area, said widened area having a greater width relative to said

narrowed area to provide said flexible strip of material with a narrowed width which defines a flexion point to control outward deformation of said flexible strip of material to said outwardly buckled configuration”. Support for the amendments incorporated into independent claim 69 is found, for example, on page 10, line 18 to page 12, line 9; page 19, line 18 to page 20, line 21; and Figures 2, 5 and 6 of the as-filed application.

As indicated above with regard to independent claim 66, Bonutti discloses a tissue retractor including a series of rectangular-shaped longitudinally extending slots 64 which in turn define a series of rectangular-shaped expanding arms 62 between adjacent pairs of the longitudinally extending slots 64. However, Bonutti fails to disclose or suggest that either of the longitudinally extending slots 64 define an expanding arm 62 therebetween has “a narrowed area and a widened area extending axially from said narrowed area”, and with “said widened area having a greater width relative to said narrowed area to provide said flexible strip of material with a narrowed width which defines a flexion point” to control outward deformation of the expanding arm 62. To the contrary, each of the longitudinally extending slots 64 has a rectangular shape defining a uniform shape and width, and not “a narrowed area and a widened area extending axially from said narrowed area”. Additionally, each of the expanding arms 62 also has a rectangular shape defining a uniform shape and width, and is not provided with “a narrowed width” via a widened area of one of the longitudinally extending slots 64 to define a flexion point to control outward deformation of the expanding arm 62. Accordingly, the Applicant submits that independent claim 69 recites features that are neither disclosed or suggest by Bonutti.

With regard to Sachdeva, as also indicated above with regard to independent claim 66, none of the disclosed devices includes “an inner actuator member disposed within an outer sleeve member, a distal portion of said sleeve member being outwardly deformed to define said transverse projections in response to relative displacement between said actuator member and said sleeve member”, as recited in independent claim 69. Furthermore, the devices disclosed in Sachdeva fail to disclose or suggest other features recited in independent claim 69. Specifically, as shown in Figures 1-4 of Sachdeva, the outwardly deformable strips of material defined between adjacent slots each have a rectangular shape defining a uniform shape and width, and are not provided with “a narrowed width” via a widened area of one of the longitudinally extending slots to define a flexion point to control outward deformation of the strips of material.



Accordingly, the Applicant submits that further reasons support the patentability of independent claim 69 over Sachdeva.

For at least the reasons set forth above, independent claim 69 is submitted to be patentable over Bonutti and Sachdeva. The Applicant therefore respectfully requests withdrawal of the rejection of independent claim 69 and allowance of the same.

Claims 70 and 101-103 depend either directly or indirectly from independent claim 69 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 69. However, further reasons support the patentability of the claims depending from independent claim 69. For example, claim 101 recites that “said widened area of said slot is defined by an arcuate portion of said slot”, claim 102 recites that “said slot has first and second widened areas with said narrowed area positioned between said first and second widened areas to provide said slot with an hour-glass shape”, and claim 103 further recites that “said hour-glass shape is defined by a series of arcuate portions of said slot extending along said longitudinal axis”.

Neither Bonutti nor Sachdeva disclose the features recited in claims 101-103. Instead, the longitudinally extending slots defined by the Bonutti and Sachdeva devices have a rectangular shape defining a uniform width and straight/non-arcuate sides which provide the longitudinally extending strips of material defined between adjacent pairs of the slots with a rectangular shape having straight sides. Indeed, none of the longitudinally extending slots have “an arcuate portion” that defines a widened area of the slot, as recited in claim 101. Additionally, none of the longitudinally extending slots have “first and second widened areas with said narrowed area positioned between said first and second widened areas” to provide the slot with “an hour-glass shape”, as recited in claim 102, or that “said hour-glass shape is defined by a series of arcuate portions of said slot extending along said longitudinal axis”, as recited in claim 103.

### CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 55-63, 65-74 and 94-103. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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